

Remarks/Arguments

Applicants thank the Patent Office for the Advisory Action mailed from the United States Patent Office on March 10, 2004. It is Applicants' understanding that the amendments to the claims made in the Response to the Office Action made Final were entered into the record for Appeal purposes. These amendments are therefore reflected in the claims presently presented.

In lieu of an Appeal brief, Applicants are presenting this RCE application and claims for further consideration. Cancellation of claims 1, 4 and 5 is not acquiescence to any rejection, but is done to help expedite the prosecution of the remaining claims. Applicants respectfully reserve the right to pursue the canceled claims in a continuation application.

Claims 1, 4 and 5 have been canceled.

Claims 11, 16 and 17 are pending and under consideration.

The various rejections, are discussed in detail below in the order raised by the Patent Office in the Office Action made Final, dated November 12, 2003 and the comments made in the Advisory Action, dated March 10, 2004.

Rejection of Claims 1, 4 and 5 under 37 C.F.R. § 103(a)

Claims 1, 4 and 5 stand rejected under 37 C.F.R. § 103(a) as being unpatentable over the combinations of JP 61000017A (hereinafter "Seikagaku"), US Patent No. 5,989,535 (hereinafter "Nayak et al.") and US Patent No. 4,443,459 (hereinafter "Yano et al.").

Claims 1, 4 and 5 are canceled, thereby obviating the basis for this rejection. Cancellation of *composition* claims 1, 4 and 5 is not acquiescence to the pending rejection but is done to help expedite the prosecution of the remaining *method of use claims*. Applicants reserve the right to pursue the canceled claims in a continuation application.

**Rejection of Claims 11, 16 and 17 under 37 C.F.R. § 103(a) based on Office Action
Made Final (November 12, 2003)**

Claims 11, 16 and 17 stand rejected under 37 C.F.R. § 103(a) as being unpatentable over the combination of Seikagaku, Nayak et al. and Yano et al. Applicants respectfully traverse the rejection for at least the following reasons.

Seikagaku discloses a hyaluronic acid composition having a molecular weight of between 4,000 and 2,000,000 daltons with a dosage of 25 mg to 5 g a day by mouth for *treatment of cancer metastasis*.

In contrast, the present invention pertains to an orally administered composition in the form of a *soft gelatin capsule* that includes hyaluronic acid and its use for *skin softening*. The dosage of the hyaluronic acid in the soft gelatin capsule is between 35 to 45 mg and has a molecular weight between 50,000 and 200,000 daltons.

Seikagaku fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that any hyaluronic acid composition could be useful as an orally administered composition useful for *skin softening*. Additionally, Seikagaku fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that a hyaluronic acid composition could be administered in a *soft gelatin capsule*, as is admitted in the Office Action Made Final. Seikagaku also fails to teach or suggest, provide any motivation or an expectation of success that a skilled artisan would choose to administer 35 to 45 mg of hyaluronic acid in a *soft gelatin capsule* for *skin softening*. Seikagaku further fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons in a *soft gelatin capsule* would be useful for *skin softening*. Furthermore, Seikagaku fails to teach or suggest, provide any motivation or an expectation of success that a hyaluronic acid composition that includes either rice bran oil or beeswax could be administered in a *soft gelatin capsule* and used for *skin softening*.

Yano et al. fail to remedy the deficiencies of Seikagaku. Yano et al. disclose the use of beeswax or rice bran oil as a diluent for α -tocopheryl esters of 5-substituted picolinic acid. α -tocopheryl esters of 5-substituted picolinic acid have no physical or chemical relationship to hyaluronic acid. The reference to Yano et al. fails to provide any teaching or suggestion that use of beeswax or rice bran oil could be used for any agent other than α -tocopheryl esters of 5-substituted picolinic acid. Yano et al. fail to provide any basis that would motivate a skilled artisan to use beeswax or rice bran oil as a diluent for anything other than α -tocopheryl esters of 5-substituted picolinic acid. Therefore, Yano et al. also fail to provide an expectation of success that such diluents could be used for any other composition other than α -tocopheryl esters of 5-substituted picolinic acid.

Yano et al. fail to teach or suggest any *skin softening* method that includes any hyaluronic acid composition.

Additionally, the Office Action asserts that Yano et al. teach the use of soft capsules. Yano et al. do not teach or suggest the use of soft *gelatin* capsules. It is unknown from the teachings of Yano et al. to what a “soft capsule” actually is. The undefined “soft capsule” could be made from polyvinyl alcohol, plant extracts, etc. The term “soft capsule” is akin to a “genus” and a “soft gelatin capsule” (that of the presently claimed invention) is a species. A genus does not anticipate or make obvious a species. The currently claimed invention has a unitary *soft gelatin* capsule that surrounds the active ingredient, hyaluronic acid.

The Office Action continues that Nayak et al. teach a composition which can be in the form of a soft gelatin capsule that includes polymers, such as hyaluronic acid.

Nayak et al. fail to remedy the deficiencies of either Seikagaku or Yano et al. Nayak et al. focus on bioadhesive emulsion compositions that deliver a drug to a target site in a sustained fashion. A polymer and a crosslinking agent are dispersed in a hydrophobic medium and then incorporated into polyethylene glycol. The dispersion is encapsulated in a soft gelatin shell. As is stated at column 3, lines 47 through 53, various polymer can be used to modify physical properties and release properties of the bioadhesive composition. Hyaluronic acid is noted as one of these “fillers”. No mention is made regarding the molecular weight, the amount of the hyaluronic acid incorporated into such a capsule, or that bee’s wax or rice bran oil could be used

in such a capsule. It is impermissible within the framework of section 103 to choose from any one reference only so much of it as will support a given position, to exclusion of other parts necessary to fully appreciation of what reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 U.S.P.Q. 391 (CCPA, 1965)

More importantly, Nayak et al. fail to teach or suggest, any *skin softening* applications whatsoever! Nayak et al. fail to provide any motivation to a skilled artisan to prepare a soft gelatin capsule having a hyaluronic acid dosage of between 35 to 45 mg and a molecular weight between 50,000 and 200,000 daltons useful for *skin softening*.

As stated previously, Seikagaku discloses a hyaluronic acid for *treatment of cancer metastasis*, such as melanoma.

Nayak et al. and Yano et al. are devoid of any teachings regarding skin applications.

None of the references, *alone or in combination*, teach or suggest, provide any motivation or an expectation of success that *skin softening* could be accomplished with a hyaluronic acid composition of any type.

None of the references, *alone or in combination*, teach or suggest, or provide any motivation or an expectation of success to a person having ordinary skill in the art that *skin softening* could be accomplished by any orally administered hyaluronic acid composition. None of the references, *alone or in combination*, teach or suggest, or provide any motivation or an expectation of success to a person having ordinary skill in the art that *skin softening* could be accomplished by a hyaluronic acid composition in a *soft gelatin capsule*. None of the references, *alone or in combination*, teach or suggest, or provide any motivation or an expectation of success that a skilled artisan would choose to administer 35 to 45 mg of hyaluronic acid in a *soft gelatin capsule* for *skin softening*. None of the references, *alone or in combination*, teach or suggest, or provide any motivation or an expectation of success to a person having ordinary skill in the art that 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons in a *soft gelatin capsule* would be useful for *skin softening*. None of the references, *alone or in combination*, teach or suggest, or provide any motivation or an expectation of success that a hyaluronic acid composition that includes either

rice bran oil or beeswax could be administered in a *soft gelatin capsule* useful for *skin softening*.

It is Applicants position that the Office Action utilizes the combination of references in view of the present invention in a hindsight analysis. Hindsight analysis is not permissible by law. The argument is made that it would be obvious to take *any compound* and place it into either beeswax or rice bran oil and/or place the combination in a soft gelatin capsule *useful for skin softening*. The Office Action fails to provide the motivation or an expectation of success why the combination of references would make such a discovery legally obvious. For example, some compounds simply do not solvate well in either beeswax or rice bran oil.

Surely the realization, for example, that a compound could be now combined with either beeswax or rice bran oil, when it may have been known to be solvated in some other diluent, would result in the non-patentability of that combination for *any compound*. This is not the correct legal standard. The ordinary skilled artisan did not know or appreciate that *skin softening* could be accomplished, in the hypothetical example, by solvating the compound in either beeswax or rice bran oil, let alone placed into a soft gelatin capsule. This analogy mirrors the present case at hand.

The discovery and surprise was that *skin softening* can be accomplished with 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons formulated in a soft gelatin. Further, there was no appreciation in the art that *skin softening* could be accomplished with hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons formulated with beeswax or rice bran oil in a soft gelatin capsule. Lastly there was no recognition of either relationship prior to the presently claimed subject matter; hence the juxtaposition of the impermissible hindsight analysis and/or use of the Applicants' own specification as a blueprint for obviousness.

This becomes an "obvious to try" analysis which is again, not permissible by law. An Applicants' specification and claims cannot be used as a blueprint to solve a previously unknown problem, and then be used against the Applicants.

Reconsideration and withdrawal are respectfully requested.

In the event that the arguments presented and amendments do not overcome the outstanding rejections, Applicants respectfully request that the amendments be made of record so that the issues may be crystallized for appeal purposes.

Advisory Action

Applicant next responds to comments provided in the Advisory Action dated March 10, 2004.

The arguments presented in the Advisory Action focus solely on *compositions*. The arguments previously presented in the Response to Office Action Made Final pertained to both compositions and methods of use, i.e., skin softening. It appears that the Advisory Action overlooked the method of use claims.

Currently, pending claims are drawn to methods of use and not compositions.

Additionally, the Advisory Action stated that previous response argued only each reference individually. That is incorrect. Each reference was discussed independently, and as combinations. In fact, the language used was "None of the references, alone or in combination..." It is respectfully requested that the previous response be reviewed for clarity. Also, it is respectfully submitted that the present response does consider the combination of references.

Conclusion


This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before April 12, 2004, along with a Request For Continued Examination and Request for Two-Month Extension, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief that may be required, or credit any overpayment to Deposit Account No. 04-1420.

Respectfully submitted,

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